

REMARKS

Claims 11, 34, and 35 are pending in the application. Claim 11 has been amended to recite that the method treats or prevents the development of atypical tissue. Support for this amendment may be found at, *inter alia*, Published Specification page 10, paragraph [0104]. The Applicant also has added new Claims 36-44. The new claims find support in the published specification as follows: Claim 36 at page 10, paragraph [0104]; Claim 37 at page 10, paragraph [0105]; Claim 38 in original Claim 19; Claim 39 in original Claim 7; and Claim 40 in original Claim 13; Claim 41 at page 10, paragraph [0105]; Claim 42 in original Claim 19; Claim 43 in original Claim 7; and Claim 44 in original Claim 13.

By way of this amendment, the Applicants do not surrender any subject matter. The Applicants reserve the right to pursue all disclosed subject matter in continuing applications. Reconsideration of the claims in light of the following remarks is respectfully requested.

35 U.S.C. §103 Rejections

Claims 11, 34, and 35 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent Application Publication No. 2001/0043930 ("Aoki") in view of "Apocrine Gland Carcinoma of the Breast," *The Australian and New Zealand Journal of Surgery*, 33(3):200-204, Feb. 1964 ("Wald"). The Applicants respectfully disagree. Since Aoki is discloses the treatment of conditions associated with muscle contraction and cholinergic controlled secretions,¹ a skilled artisan would not be motivated by to use botulinum toxin to treat or prevent the development of atypical tissues, such as hyperplastic tissues, cysts and neoplasms (including tumors and cancers).² All pending claims are directed to treating or preventing the development of atypical tissues.

Aoki does not motivate a skilled artisan to treat or prevent atypical tissue development with botulinum toxin. The Examiner cites Aoki's Example 5, as relevant to the present claims. Example 5 states, "[s]weating and tearing are under greater

¹ Aoki, p. 1, ¶ [0014].

² Published Specification, p. 10, ¶ [0104].

cholinergic control than mucus or gastric secretion" but, "mucus and gastric secretions could be modulated through the cholinergic system."³ This example discusses cholinergic influence on the secretion of sweat, tears, mucus and gastric fluid not the development of atypical tissue. Wald does nothing to bridge the gap between the secretion of sweat, for example, and the development of atypical tissue.

The Examiner states that a skilled artisan (presumably deducing a connection between sweat glands and apocrine glands, which are located in the mammary glands), would have combined the teachings of Aoki and Wald. However, a skilled artisan would know that apocrine glands and sweat glands function differently and have different roles in the body. Indeed, a skilled artisan mistakenly applying the teachings of Aoki to Wald would have been redirected by Wald's statement that "apocrine glands are not sweat glands; their function in man has no bearing on the control of body temperature and they do not excrete large amounts of water and metabolites."⁴ In other words, Wald directs the skilled artisan not to combine its teachings with teachings related to sweat glands. Neither Aoki nor Wald motivates a skilled artisan to treat or prevent "atypical" tissue development with botulinum toxin; and, Wald teaches away from its combination with Aoki. Accordingly, since Aoki and Wald cannot render the present claims obvious, the Applicants respectfully request reconsideration and withdrawal of this rejection.

³ Aoki, p. 4, ¶ [0061].

⁴ Wald, p. 203, bottom of left column.

CONCLUSION

The Applicants believe this application is in condition for allowance. Accordingly, the Applicants respectfully request that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Should any issues remain, the Examiner is invited to call the Applicants' undersigned representative.

Respectfully submitted,

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